K113720

SEP 20 2012

510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacturer and Submitter

Name: Randox Laboratories Limited

Address: 55 Diamond Road, Crumlin,
County Antrim, BT29 4QY,
United Kingdom.

Telephone: +44 (0) 28 9442 2413
Fax: +44 (0) 28 9445 2912
E-mail: marketing@randox.com

Device Name

Trade Name: Randox Maternal Controls Levels 1, 2 and 3

Common Name: Maternal Controls Levels 1, 2 and 3

Classification: Multianalyte Controls, All kinds (Assayed and Unassayed)

Product Code: JJY

Date of Summary Preparation

28th August 2012

Predicate Devices

Bio-Rad Lyphochek Maternal Serum Controls Levels 1, 2 and 3

Device Description

Randox Maternal Controls are manufactured at three levels, Level 1, Level 2 and Level 3. The analyte concentrations in each of the three levels have been chosen to span a range that includes the chemically significant or medical decision level(s). The analyte concentrations have been reviewed by a panel of experts to ensure that the concentrations are clinically relevant for use in routine hospital laboratories.

Intended Use

The Randox Maternal Controls Level 1, Level 2 and Level 3 are intended for *in vitro* diagnostic use in the quality control of Unconjugtaed Estriol and Total ß-Human Chorionic Gonadotrophin methods on clinical chemistry systems.

Similarity to Predicate Device

- Both are assayed quality control serums.
- Both are intended to monitor the precision of laboratory testing procedures for the analytes named in the product insert.
- Both are in vitro diagnostic devices.
- Both devices are in lyophilised format and manufactured from human serum.

Stability

Accelerated stress tests have been used to predict shelf life for controls stored routinely at +2 - +8°C. A control stored at 37°C for 1 week is tested against the control stored at routine temperature and recovery assessed. If a percentage deviation between stressed and routine is below 10% then a 1 year shelf life would be assigned to the control. For every week stressed at 37°C that passed these criteria then 1 year shelf life would be added.
i.e. Controls stored for 3 weeks at 37°C which passed criteria would be given 3 years of shelf life.

Conclusion

Testing results indicate that the proposed device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Randox Laboratories
c/o Pauline Armstrong
55 Diamond Rd.
Crumlin, County Antrim
United Kingdom BT29 4QY

SEP 20 2012

Re: k113720
Trade Name: Randox Maternal Controls Level 1, Level 2 and Level 3
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: September 7, 2012
Received: September 10, 2012

Dear Dr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

RANDOX

Indications for Use

510(k) Number (if known): K113720

Device Name: Randox Maternal Controls Level 1, Level 2 and Level 3

Indication for Use:

The Randox Maternal Controls Level 1, Level 2 and Level 3 are intended for *in vitro* diagnostic use in the quality control of Unconjugtaed Estriol and Total ß-Human Chorionic Gonadotrophin methods on clinical chemistry systems.

This in vitro diagnostic device is intended for prescription use only.

Prescription Use ✓ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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